IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, et al.,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC, et al.,

Defendants.

Case No.: 1:20-cv-00706-DLC

Plaintiff States' Supplemental Pretrial Memorandum of Law

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PRELIMINARY STATEMENT

Defendants' anticompetitive scheme is an egregious violation of state and federal law. The wrongdoing was clearly and intentionally anticompetitive, and had no legitimate procompetitive, pro-consumer, or pro-patient benefit. Daraprim is not a dangerous, sensitive, fragile, or controlled substance that warrants the distribution restrictions and monitoring that Defendants employed. Similarly, Defendants' efforts to lock up all manufacturers of the active pharmaceutical ingredient ("API") for Daraprim were not justified by any *bona fide* supply concerns. And, Defendants' attempts to block generic competitors from accessing the data necessary to evaluate the market opportunity for generic Daraprim likewise lacked any legitimate motive. Rather, the purpose and effect of every facet of this illegal scheme was to restrain competition.

Defendants infamously bought the rights to an old, unpatented, life-saving drug and immediately increased its price by more than 4000%. While not in itself illegal, this type of dramatic price increase would normally attract fierce generic price competition. Defendants foresaw and forestalled this by engaging in numerous practices and agreements designed to prevent, impede, and delay potential generic competition. First, Defendants entered into numerous agreements restricting (or even prohibiting) resale of Daraprim by distributors, hospitals, and other downstream purchasers of Daraprim to hinder potential generic competitors' ability to obtain sufficient drug product to conduct the testing necessary to obtain FDA approval of a generic Daraprim. Second, Defendants expended substantial time and resources to obtain exclusive agreements with the most viable API sources to both dissuade potential generic competitors from attempting to enter the market and delay generic entry. Third, Defendants paid two of their primary distributors not to transfer their Daraprim sales data to third-party aggregators in order to obscure the size of the market opportunity in hopes that this would chill

generic entry (as potential generic competitors rely on such data in making launch decisions).

Defendants even went so far as to buy back their own product, at even more elevated prices, in a surreptitious and dubious parking lot meet-up – just to keep it out of the hands of competitors.

See Plaintiffs' Pretrial Proposed Findings of Fact ("FOF") ¶ 77.

These facts and circumstances stand out for their inequity and greed – and for Defendants' stunning and unrepentant disregard for state and federal law. The State of New York, State of California, State of Illinois, State of North Carolina, State of Ohio, Commonwealth of Pennsylvania, and Commonwealth of Virginia (collectively, "Plaintiff States") brought this action to hold Defendants accountable, deter similar conduct and deprive the wrongdoers of their ill-gotten gains. Accordingly, we are requesting that the Court denounce Defendants' anticompetitive business practices and grant the relief that the Plaintiffs have outlined in their Proposed Order, including an order enjoining this conduct with regard to Daraprim or any other pharmaceutical product, banning the individual defendants from participation in the pharmaceutical industry, and requiring the disgorgement of all ill-gotten gains as detailed below.

Moreover, since the misconduct is fully and inseparably attributable to all four corporate and individual Defendants, the Defendants can and should be held jointly and severally liable. This is a unitary scheme, and no Defendant is responsible for less than all of the harm. Their conduct, individually and collectively, is egregious and warrants the imposition of joint and several liability for equitable monetary relief. Doing so would be consistent with long-standing equitable principles set forth in case law, including the recent Supreme Court case *Liu v. SEC*, 140 S.Ct. 1936 (2020).

ARGUMENT

Defendants' conduct violates the laws of the various Plaintiff States, as well as federal law. ECF No. 86 at 67-74 (Am. Complaint Counts IV-X); *see also* Plaintiffs' Joint Pretrial Memorandum at 12-43 (discussing federal law). Plaintiffs' Joint Pretrial Memorandum sets out the factual and legal bases for concluding that Defendants' conduct violated federal antitrust law and explains why an injunction against all Defendants and a ban against the individual defendants is necessary and appropriate. *Id.* For the same reasons that Defendants' anticompetitive scheme violates federal law, the conduct likewise violates each of the state laws asserted in the Amended Complaint.¹

The Court has already ruled that the Plaintiff States, by their Attorneys General, have standing to bring these state (and federal) claims, and to seek equitable relief. ECF No. 229; ECF No. 482; ECF 483. This memorandum explicates Defendants' liability under the various state laws asserted in the Amended Complaint, ECF No. 86, and demonstrates that the equitable relief sought by Plaintiff States – namely, injunctive relief, the disgorgement of ill-gotten gains, and a ban on industry participation for the individual defendants – is legally authorized, necessary, and appropriate in this case.

I. Defendants' Anticompetitive Conduct Violates State Laws

Defendants' anticompetitive agreements and unlawful scheme to impede and delay generic competition violate each of the State laws asserted in the Amended Complaint for the same reasons they violate the federal antitrust laws. *See* Plaintiffs' Joint Pretrial Memorandum,

¹ New York's Donnelly Act, N.Y. Gen. Bus. Law § 340 et seq.; N.Y. Exec. Law § 63(12); California's Cartwright Act, CA Bus & Prof Code § 16700 et seq., California's Unfair Competition law, CA Bus & Prof Code § 17200 et seq.; Illinois Antitrust Act, 740 ILCS 10/1 et seq.; North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. § 75-1 et seq.; Ohio's Valentine Act; Ohio Revised Code §1331.01 et seq.; Pennsylvania's Common Law Doctrine against Restraints of Trade; and Virginia Antitrust Act, Virginia Code § 59.1-9.1 et seq.

incorporated by reference. Plaintiff States here identify and discuss the relevant state laws violated by Defendants' anticompetitive conduct in more detail.

A. New York

Defendants' anticompetitive practices, agreements and overall course of conduct to maintain monopoly power over FDA-approved pyrimethamine products, as detailed in Plaintiffs' Findings of Facts, violate New York's Donnelly Act, N.Y. Gen. Bus. Law §§ 340-347, as well as New York Executive Law § 63(12).

The Donnelly Act is New York's antitrust statute, enacted more than a century ago shortly after the enactment of the federal Sherman Act. *State v. Mobil Oil*, 38 N.Y.2d 460, 463 (N.Y.1976) (Donnelly Act enacted in 1893, three years after the Sherman Act). The Donnelly Act declares illegal:

Every contract, agreement, arrangement or combination whereby. . . [c]ompetition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained or whereby. . . for the purpose of establishing or maintaining any such monopoly or unlawfully interfering with the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state any business, trade or commerce or the furnishing of any service is or may be restrained.

N.Y. Gen. Bus. Law §340(1). "The purpose of the section is to prevent restraint of trade and the creation of monopoly so as to protect the general public against enhanced prices of essential commodities by suppression of competition." *Purofied Down Products Corp. v. National Ass'n of Bedding Mfrs.*, 201 Misc. 149, 156 (N.Y. Sup. Ct. 1951).

The "Donnelly Act has been considered to have been modeled after the [federal] Sherman Act," *Mobil Oil*, 38 N.Y.2d 460 at 463, and New York's highest court has held that it "should generally be construed in light of Federal precedent and given a different interpretation only where State policy, differences in the statutory language or the legislative history justify

such a result." *People v. Rattenni*, 81 N.Y.2d 166, 171 (N.Y. 1993) (citing *Anheuser-Busch, Inc. v. Abrams*, 71 N.Y.2d 327, 335 (N.Y. 1988)).

The Executive Law authorizes the New York Attorney General to sue "any person' who engages in 'repeated fraudulent or illegal acts or otherwise demonstrate[s] persistent fraud or illegality." *State v. Apple Health and Sports Club*, Ltd., 80 N.Y.2d 803, 807 (N.Y. 1992) (quoting N.Y. Exec. Law § 63(12)). The "illegal acts" or "illegality" may be violations of state or federal laws. *See, e.g., id.* (violations of health club licensing laws); *see also State v. Princess Prestige Co.*, 42 N.Y.2d 104 (1977) (violations of the Home Solicitation Sales Act); *People v. Applied Card Sys., Inc.*, 27 A.D.3d 104 (3d Dep't 2005), *aff'd on other grounds*, 11 N.Y.3d 105 (2008) (violations of debt collection laws); *State v. Frink Am.*, Inc., 770 N.Y.S.2d 225 (App. Div. 4th Dep't 2003) (violations of labor laws). Federal Sherman Act and New York Donnelly Act violations have been held to be a valid bases for an action and relief under the Executive Law. *New York v. Actavis*, 2014 WL 7015198, *43, 2014 U.S. Dist. LEXIS 172918 (S.D.N.Y. Dec. 11, 2014), *aff'd on other grounds*, 787 F.3d 638 (2d Cir. 2015); *New York v. Feldman*, 210 F. Supp. 2d 294, 300 (S.D.N.Y. 2002).

The Attorney General may seek an order enjoining the illegal acts and associated conduct, obtain equitable monetary relief (including disgorgement of ill-gotten gains), and may permanently ban individual violators from further involvement in the industry. *See, e.g., People ex rel. Schneiderman v. Greenberg*, 27 N.Y.3d 490, 497 (N.Y. 2016) (construing the Executive Law to include the remedy of disgorgement); *People ex rel. Schneiderman v. Imported Quality Guard Dogs, Inc.*, 930 N.Y.S.2d 906, 907-08 (App. Div. 2d Dep't 2011) (affirming order permanently enjoining defendant from engaging in the business of dog selling, breeding, or training).

B. California

Defendants' anticompetitive conduct, including their vertical arrangements and API exclusivity agreements, unreasonably restrained trade in violation of both California's antitrust statute, the Cartwright Act, Cal. Bus. & Prof. Code § 16700 et seq., and its unfair competition law (the "UCL"), Cal. Bus. & Prof. Code § 17200 et seq. Under California law, "antitrust violations are torts" and "corporate officers are liable for their tortious acts committed on behalf of the corporation." Classen v. Weller, 145 Cal. App. 3d 27, 48, 192 Cal. Rptr. 914 (Cal. Ct. App. 1983). Though "broader in range and deeper in reach than the Sherman Act" (In re Cipro Cases I & II, 61 Cal. 4th 116, 160, 187 Cal. Rptr. 3d 632, 348 P.3d 845 (Cal. 2015) (internal quotations and citations omitted)), the Cartwright Act, like its federal counterpart, prohibits all combinations created for or carrying out unreasonable restrictions in trade or commerce. See Cal. Bus. & Prof. Code § 16720(a); see also In re Cipro Cases I & II, 61 Cal. 4th at 136-137. Such prohibited combinations under the Cartwright Act include exclusive dealing arrangements. See Pecover v. Electronics Arts Inc., 633 F. Supp. 2d 976, 983 (N.D. Cal. 2009) (finding that, under California law, "[v]ertical restraints, including exclusive dealing arrangements, are proscribed when it is probable that performance of the arrangements will foreclose competition in a substantial share of the affected line of commerce.") (citing Fisherman's Wharf Bay Cruise Corp. v. Superior Court, 114 Cal. App. 4th 309, 334-35, 7 Cal. Rptr. 3d 628 (Cal. Ct. App. 2003)). For actions brought by the Attorney General, courts may "grant such mandatory injunctions as may be reasonably necessary to restore and preserve fair competition in the trade or commerce affected by the violation." Cal. Bus. & Prof. Code § 16754.5.

The UCL is broad by design and prohibits "acts or practices which are unlawful, or unfair, or fraudulent." Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co., 20 Cal. 4th 163, 180-81, 83 Cal. Rptr. 2d 548, 973 P.2d 527 (Cal. 1999). The unlawful prong "borrows violations of other laws and treats them as unlawful practices" under the UCL. *Id.* at 180 (citations omitted). Under the unfair prong, "a practice may be deemed unfair even if not specially proscribed by some other law" and even if not violating an antitrust statute. *Id.* at 180, 187. To determine whether a business practice is unfair, courts traditionally have applied a balancing test, weighing "the utility of the defendant's conduct against the gravity of the harm to the alleged victim." Drum v. San Fernando Valley Bar Ass'n, 182 Cal. App. 4th 247, 257, 106 Cal. Rptr. 3d 46 (Cal. Ct. App. 2010) (internal quotations and citations omitted). In Cel-Tech, the California Supreme Court announced a test for "unfairness" in antitrust cases between competitors, requiring the plaintiff to show that the challenged conduct (1) "threatens an incipient violation of an antitrust law," (2) "violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law," or (3) "otherwise significantly threatens or harms competition." Cel-Tech, 20 Cal. 4th at 187. These findings must be "tethered to some legislatively declared policy or proof of some actual or threatened impact on competition." Id. at 186-87. Although the Court limited its holding to competitor cases, it has been applied in noncompetitor cases. See Epic Games, Inc. v. Apple Inc., 2021 U.S. Dist. LEXIS 172303, at *289-98 (N.D. Cal. Sept. 10, 2021) (concluding the challenged conduct was unfair under both tests).

C. Illinois

Defendants' anticompetitive activities, including their vertical arrangements and API exclusivity agreements, restrained trade and violated the Illinois Antitrust Act ("IAA") for the same reasons they violate the Sherman Act. The IAA instructs Illinois courts to use federal court

interpretations of the Sherman Act as a guide to interpret similar provisions of the IAA. 740 ILCS 10/11. Following this principle, Illinois courts have held that Sections 3(2) and 3(3) of the IAA are comparable to Sections 1 and 2 of the Sherman Act and require the same elements of liability. Gilbert's Ethan Allen Gallery v. Ethan Allen, Inc., 162 Ill. 2d 99, 108 (1994); Boffa Surgical Group LLC v. Managed Healthcare Assocs., 2015 IL App (1st) 142984, ¶ 19 (2015) (construing Section 3(2) of the IAA in accordance with Section 1 of the Sherman Act); A&A Disposal & Recycling, Inc. V. Browning-Ferris Indus. Of Ill., Inc., 279 Ill. App. 3d 337, 341 (2d Dist. 1996) (construing Section 3(3) of the IAA as comparable to Section 2 of the Sherman Act); accord Acuity Optical Labs., LLC v. Davis Vision, Inc., 2016 U.S. Dist. LEXIS 112423, *58 (C.D. Ill. August 23, 2016).

Section 10/7(1) of the IAA authorizes the Illinois Attorney General to bring actions to prevent and restrain violations of Section 3 of the IAA, and courts are directed to enter such judgment as they consider necessary to remove the effects of any such violations. 740 ILCS 10/7(1). Under the IAA, Courts are authorized to exercise all powers necessary for this purpose, including, but not limited to, issuing injunctions and divesting property. *Id*.

D. North Carolina

The North Carolina Attorney General is authorized to investigate "all corporations or persons doing business in this State...with the purpose of acquiring such information as may be necessary to enable him to prosecute any such corporation, its agents, officers and employees for crime, or prosecute civil actions against them if he discovers they are liable and should be prosecuted." N.C. Gen. Stat. § 75-9; *State ex rel. Easley v. Rich Food Servs.*, Inc., 139 N.C. App. 691, 535 S.E.2d 84 (2000) (corporation's managing agent, even though not an officer or director, may properly be sued for violations of this chapter committed under his management).

The body of law applying the Sherman Act, although not binding on state courts, is nonetheless instructive in determining the full reach of N.C. Gen. Stat. § 75-1. *North Carolina Steel, Inc. v. National Council on Comp. Ins.*, 123 N.C. App. 163, 472 S.E.2d 578 (1996), *aff'd in part and rev'd in part*, 347 N.C. 627, 496 S.E.2d 369 (1998); *Rose v. Vulcan Materials Co.*, 282 N.C. 643, 194 S.E.2d 521 (1973); *Hester v. Martindale-Hubbell, Inc.*, 493 F. Supp. 335 (E.D.N.C. 1980), *aff'd*, 659 F.2d 433 (4th Cir. 1981). The North Carolina antitrust enforcement mechanism almost completely mirrors its federal counterpart. *Nash County Bd. of Educ. v. Biltmore Co.*, 464 F. Supp. 1027 (E.D.N.C. 1978), *cert. denied*, 454 U.S. 878, 102 S. Ct. 359, 70 L. Ed. 2d 188, *rehearing denied*, 454 U. S. 1117, 102 S. Ct. 692, 70 L. Ed. 2d 654 (1981), *aff'd*, 640 F.2d 484 (4th Cir. 1981).

Actual injury is not required in an action brought under this chapter by the Attorney General. Instead, the action must show that defendant's conduct adversely affects the public interest. *State ex rel. Edmisten v. Challenge, Inc.*, 54 N.C. App. 513, 284 S.E.2d 333 (1981).

The court is authorized to "order the restoration of any moneys or property and the cancellation of any contract obtained by *any defendant* as a result of such violation." N.C. Gen. Stat. § 75-15.1 (emphasis added); *State ex rel. Easley v. Rich Food Servs.*, Inc., 139 N.C. App. 691, 699, 535 S.E.2d 84, 90 (2000). This provision has been held to authorize disgorgement. *FTC v. Mylan Labs.*, 62 F. Supp. 2d 25, 61-62 (D.D.C.1999). Further, "[t]he Attorney General may prosecute civil actions in the name of the State to obtain mandatory orders, including (but not limited to) permanent and temporary injunctions and temporary restraining orders, to carry out the provisions of [Chapter 75]." N.C. Gen. Stat. § 75-14; *State ex rel. Easley v. Rich Food Servs.*, Inc., 139 N.C. App. 691, 697, 535 S.E.2d 84, 88 (2000).

E. Ohio

Defendants' activities, including restrictions and limitations on the resale of Daraprim and API exclusivity agreements, restrain trade in violation of Ohio's Valentine Act. "The Ohio Valentine Act (R.C. § 1331.01, et. seq.) is patterned after the Sherman Act and Ohio courts consistently interpret the Valentine Act in accordance with federal judicial construction of the federal antitrust laws." Hogan v. Cleveland Ave Rest., Inc., 2018 U.S. Dist. LEXIS 49587, at *9 (S.D. Ohio Mar. 26, 2018). See also Johnson v. Microsoft Corp., 106 Ohio St. 3d 278, 2005-Ohio 4985, 834 N.E.2d 791, 797 (Ohio 2005); C. K. & J. K, Inc. v. Fairview Shopping Ctr. Corp., 63 Ohio St. 2d 201, 407 N.E.2d 507, 509 (Ohio 1980) ("These statutes, known as the Valentine Act, were patterned after the Sherman Antitrust Act, and as a consequence this court has interpreted the statutory language in light of federal judicial construction of the Sherman Act") (citations omitted). "The Valentine Law was passed April 19, 1898, and is generally conceded to have been patterned after the Sherman Anti-Trust Act of July 2, 1890...[a] comparison of the two enactments shows that the Ohio law is in much broader and stronger terms than the federal enactment. "List v. Burley Tobacco Growers' Co-op. Ass'n, 151 N.E. 471, 474 (Ohio 1926).

The Ohio Attorney General has an affirmative duty to "do all things necessary" to enforce the antitrust laws, by bringing suits for "equitable relief," O.R.C. § 109.81, or "to restrain and enjoin" violations, or by seeking to have violations "enjoined or otherwise prohibited," or through "injunction or other proceedings," *id.* § 1331.11. There are no limitations on the kinds of equitable relief that Ohio may seek or that this Court can grant. *See generally* O.R.C. Chapter 1331; O.R.C. § 109.81. "Federal courts are courts in law and in equity, and a court of equity has traditionally had the power to fashion any remedy deemed necessary and appropriate to do justice in a particular case." *Carter-Jones Lumber Co. v. Dixie Distrib. Co.*, 166 F.3d 840, 846

(6th Cir. 1999); see also FTC v. Mylan Labs., Inc., 99 F. Supp. 2d 1, 8 (D.D.C. 1999) (confirming Ohio's right to seek an equitable remedy in an antitrust action).

F. Pennsylvania

Defendants' conduct violates Pennsylvania's common law doctrine against unreasonable restraint of trade. The Commonwealth of Pennsylvania, by and through its Attorney General, can bring an antitrust action on behalf of the general economy of the Commonwealth for a violation of state common law antitrust. Commonwealth Attorneys Act, 71 P.S. § 732-204 (c). In Collins v. Main Line Board of Realtors, 304 A.2d 493, 496 (Pa. 1973), the Pennsylvania Supreme Court applied federal court interpretation of the Sherman Act to decide a state common law antitrust claim. The Court held that, to establish a violation, the plaintiff may show that "the illegal bargain tends to create or has for its purpose to create a monopoly in prices or products," or that "competition has in fact been restricted by the monopolistic agreement." *Id.* at 496-97. *See also*, Schwartz v. Laundry & Linen Supply Drivers' Union, Local 187, 14 A.2d 438, 441 (Pa. 1940) (the Sherman Act is "merely the application of the common-law doctrine concerning restraint of trade to the field of interstate commerce."). In Huberman v. Warminster Township, 1981 WL 820, at *2-*3 (Pa. Com. Pl. Jan. 30, 1981), the Court of Common Pleas recognized that the Pennsylvania Supreme Court in Collins held that the federal Sherman Act embodied Pennsylvania's common law doctrine concerning restraint of trade and applied federal case law interpreting the Sherman Act to a Pennsylvania common law antitrust claim. The District Court for the Eastern District of Pennsylvania also followed Collins in Yeager's Fuels v. Pennsylvania Power & Light, 953 F. Supp. 617, 668 (E.D. Pa. 1997) by applying federal case law to state common law claims. Accordingly, a violation of Section 1 of the Sherman Act should be deemed a violation of Pennsylvania's common law doctrine against unreasonable restraint of trade.

The full panoply of equitable relief is available under Pennsylvania common law antitrust doctrine. Injunctive relief is available for persons who have been or will be injured by a restraint of trade or monopoly. Schwartz, 14 A.2d at 439-40. Additionally, the Commonwealth can seek monetary equitable relief for a common law antitrust violation. Order on Preliminary Objections, Commonwealth v. Chesapeake Energy, Inc. et al., No. 2015IR0069 (Bradford County Ct. Com Pl., Dec. 14, 2017). "Where equity assumes jurisdiction for one or more purposes, it will retain jurisdiction for all purposes to give complete relief and to do complete justice between the parties." Piercing Pagoda, Inc. v. Hoffner, 465 Pa. 500, 351 A.2d 207 (1976) (emphasis retained). Equity provides complete relief inclusive of a monetary award. Solomon v. Cedar Acres E., Inc., 455 Pa. 496, 501 (1974). Federal courts are vested with the inherent equitable authority to award disgorgement. *United States v. Keyspan Corp.*, 763 F. Supp. 2d 633, 638–40 (S.D.N.Y. 2011). There is no Pennsylvania state antitrust statute that limits the equitable jurisdiction of any state or federal court to award monetary equitable relief, including disgorgement, for a violation of Pennsylvania's common law doctrine against unreasonable restraint of trade and monopolies.

G. Virginia

Defendant's conduct, including their vertical arrangements and API exclusivity agreements, restrained trade and violated the Virginia Antitrust Act (the VAA). Section 59.1-9.17 of the VAA requires that the statute "shall be applied and construed to effectuate its general purposes in harmony with judicial interpretations of comparable federal statutory provisions." For the purposes of such analysis, Virginia courts have consistently held that the VAA is "comparable to the Sherman and Clayton Acts." *Com. of Va. v. Winslow*, No. 20943, 1987 WL 92058, at *2 (Va. Cir. Ct. Feb. 20, 1987); *see also Integrity Auto Specialists, Inc. v. Meyer*, 83

Va. Cir. 119 (2011); Oksanen v. Page Mem'l Hosp., 945 F.2d 696, 710 (4th Cir. 1991); Net Realty Holding Trust v. Franconia Properties, Inc., 544 F. Supp. 759, 767 n.10 (E.D. Va. 1982). Virginia Code § 59.1-9.5, which provides that "[e]very contract, combination or conspiracy in restraint of trade or commerce of this Commonwealth is unlawful," parallels Section 1 of the Sherman Act, and Section § 59.1-9.6, which provides that "[e]very conspiracy, combination, or attempt to monopolize, or monopolization of, trade or commerce of this Commonwealth is unlawful" parallels Section 2 of the Sherman Act, 15 U.S.C. § 2. Accordingly, claims under the VAA are governed by the same standard as claims under the Sherman Act, and the Court should deem violations of Section 1 and 2 of the Sherman Act to be violations of the parallel provisions of the VAA.

The Virginia Attorney General may seek "injunctive relief" for violations of the Act.

Virginia Code § 59.1-9.15(a). In Virginia, injunctive relief includes both prohibitory injunctions, which are designed to prevent a future wrong, and mandatory injunctions, which are designed to "undo an existing wrongful condition." WTAR Radio—TV Corp. v. City Council of Va. Beach,

223 S.E.2d 895, 898 (Va. 1976); Columbia Gas Transmission, LLC v. Ott, 984 F. Supp. 2d 508,

516 n.5 (E.D. Va. 2013). The VAA specifically authorizes courts to "grant mandatory injunctions reasonably necessary to eliminate violations" of the Act. Virginia Code § 59.1-9.8.

This authority is explicitly granted in addition to the authority in this Section to grant other forms of relief including "temporary restraining orders and injunctions to prevent and restrain violations of this chapter," "damages," and "civil penalties," a distinction that confirms power of the equity court to provide complete relief, including equitable monetary relief. Id.

II. Equitable Remedies of An Injunction, Disgorgement, and a Ban Are Authorized by State Law and Are Necessary and Appropriate in This Matter.

Mindful that this Court has already held that the conduct here is New York-centric ("To the extent the defendants violated either the federal or state statutes at issue here, they did so from decisions made and contracts executed in New York"), ECF 482 at 11, and that Plaintiff State of New York "may obtain disgorgement of Vyera's net profits" upon proving a violation of its state laws, ECF 482 at 14, this Section evaluates the remedies sought pursuant to New York law. Plaintiff States incorporate by reference the arguments in support of the requested relief under the laws of the other Plaintiff States, as set forth in the opposition to Defendants' unsuccessful Motion for Partial Summary Judgment. ECF No. 475.

A. Injunction

New York asserts two independent statutory bases to support its request for injunctive relief. First, pursuant to the Donnelly Act, codified in the New York General Business Law, the Attorney General may seek and obtain an order on behalf of the State "to restrain and prevent the doing in this state of any act herein declared to be illegal, or any act in, toward or for the making or consummation of any contract, agreement, arrangement or combination herein prohibited."

N.Y. Gen. Bus. Law § 342. Second, pursuant to Section 63(12) of the New York Executive Law, New York may seek "an order enjoining the continuance of [illegal or fraudulent] business activity or of any fraudulent or illegal acts." N.Y. Exec. Law § 63(12).

These statutes, by their language, do not limit the Attorney General's ability to seek injunctive relief to discrete illegal acts, but rather permit broad injunctions against business conduct associated with the illegality. *See* N.Y. Gen. Bus. Law § 342 (injunction may prohibit "any act in, toward or for the making or consummation of" anticompetitive agreements or

arrangements); N.Y. Exec. Law § 63(12) (courts may issue an "order enjoining the continuance of such business activity", not just specific acts).

The misconduct here is egregious, consisting of clear and intentional efforts to impede and delay generic competition over several years, by constructing a web of restrictive distribution agreements, supply agreements and data-blocking agreements. The result was not just an exorbitant and artificially high price for Daraprim (FOF ¶ 148), but also the creation of unnecessary risk to vulnerable patients. FOF ¶¶ 268, 270, 274, 276-77. To meet the needs of both specific and general deterrence, New York respectfully urges the Court to issue the broadest possible injunction – against all Defendants – to permanently enjoin such anticompetitive practices, in any form, including with respect to conduct concerning other pharmaceutical products, and to ban the individual Defendants from participation in the pharmaceutical industry permanently, or for at least 20 years.

B. Disgorgement

1. Disgorgement of the Totality of Defendants' Ill-Gotten Gains is Appropriate

The Supreme Court has confirmed that disgorgement, a remedy that is "a mainstay of equity courts," is "tethered to a wrongdoer's net unlawful profits." *Liu v. SEC*, 140 S. Ct. 1936, 1943 (2020). It is based on the "foundational principle" that "it would be inequitable that a wrongdoer should make a profit out of his own wrong." *Id.* (quoting *Root v. Railway Co.*, 105 U.S. 189, 207 (1882)); *see also SEC v. Commonwealth Chem. Secs., Inc.*, 574 F.2d 90, 102 (2d Cir. 1978) (disgorgement is "a method of forcing a defendant to give up the amount by which he was unjustly enriched"). Disgorgement focuses on the *gain* to the wrongdoer as opposed to the loss to the victim. ECF 482 at 12-13 (quoting *People v. Ernst & Young, LLP*, 980 N.Y.S.2d 456, 456 (1st Dep't 2014)). "Accordingly, the remedy of disgorgement does not require a showing or

allegation of direct losses to consumers or the public; the source of the ill-gotten gains is immaterial." *Id.* (citing *Ernst & Young*).

This Court has already held that:

- Disgorgement is appropriate under the Executive Law for persistent or repeated violations of the Donnelly Act or other state or federal laws. ECF 482 at 11-12.²
- The New York Attorney General has the authority to seek disgorgement of Defendants' net profits. ECF No. 482 at 11.3
- Because "the source of the ill-gotten gains is immaterial," disgorgement may include all of defendant's unjust gains attributable to the entirety of its U.S. sales. ECF No. 482 at 14.4
- In this case, the Defendants' conduct has a sufficient factual nexus with New York:

"The locus of the defendants' alleged wrongful activity was New York State. The headquarters of Vyera Pharmaceuticals, LLC were and are located in New York State. The distribution agreements at issue were executed on defendants' behalf in New York, as were the exclusive supply agreements that the plaintiffs allege were integral to the scheme." ECF 482 at 5-6. See also FOF ¶ 2.

These rulings are now the law of the case. See ECF No. 483 at 2. Thus, upon a finding of liability, the New York Attorney General may obtain disgorgement of Defendants' net profits attributable to their ill-gotten gains for the entirety of its U.S. sales. ECF No. 482 at 14.

² See, e.g., New York v. Feldman, 210 F. Supp. 2d 294, 300 (S.D.N.Y. 2002) (enforcing Donnelly Act violation); Spitzer v. Coventry First LLC, No. 0404620/2006, 2007 WL 2905486 (N.Y. Sup. Ct. Sept. 25, 2007), aff'd, 861 N.Y.S.2d 9, 10 (1st Dep't 2008) (enforcing the Donnelly Act and the Martin Act); People ex rel. Spitzer v. Telehublink Corp., 756 N.Y.S.2d 285, 285 (3d Dep't 2003) (enforcing the federal Telemarketing Act, 15 U.S.C. §6103(a) and the New York Deceptive Practices Act); State by Abrams v. Camera Warehouse, Inc., 496 N.Y.S.2d 659, 660 (N.Y. Sup. Ct. 1985) (enforcing N.Y. Gen. Bus. Law § 518); People by Vacco v. Lipsitz, 663 N.Y.S.2d 468, 474 (N.Y. Sup. Ct. 1997) (enforcing the New York Deceptive Practices and False Advertising Acts, N.Y. Gen. Bus. Law §§ 349, 350).

³ People ex. rel. Schneiderman v. Greenberg, 27 N.Y.3d 490, 497 (N.Y. 2016)). This authority stems from "New York's vital interest in securing an honest marketplace, which is threatened when a defendant uses a New York business to engage in its scheme." *Id.* at 13 (quoting *People ex rel. Cuomo v. H & R Block, Inc.*, 870 N.Y.S.2d 315, 316 (1st Dep't 2009) and *New York v. Feldman*, 210 F. Supp. 2d 294, 303 (S.D.N.Y. 2002)) (internal quote marks omitted).

⁴ This authority stems from "New York's vital interest in securing an honest marketplace, which is threatened when a defendant uses a New York business to engage in its scheme." ECF 482 at 13 (quoting *People ex rel. Cuomo v. H & R Block, Inc., 870 N.Y.S.2d 315, 316* (1st Dep't 2009) and *New York v. Feldman, 210 F. Supp. 2d 294, 303* (S.D.N.Y. 2002)) (internal quote marks omitted).

2. An Award of Equitable Monetary Relief of \$64.6 Million is Warranted

The amount to be disgorged will be "calculate[d] ... by taking the amount of profits

Defendants made in the real wor[ld] and subtracting the estimated amount of profits they would
have made if they had faced generic competition at an earlier date." ECF No. 172 at 2 (internal
quotes omitted); see also ECF No. 482 (disgorgement is "measured by the defendant's wrongful
gain.") (quoting Liu v. SEC, 140 S. Ct. 1936, 1943 (2020)). "The district court has broad
discretion not only in determining whether or not to order disgorgement but also in calculating
the amount to be disgorged." SEC v. First Jersey Secs., 101 F.3d 1450, 1474-75 (2d Cir. 1996).

The methodology for calculating disgorgement is well-established. The Second Circuit applies a two-step burden-shifting framework to calculate disgorgement. First, the plaintiff must show "that its calculations reasonably approximated the amount of the defendant's unjust gains." *FTC v. Bronson Partners, LLC*, 654 F.3d 359, 368 (2d Cir. 2011) (internal quotation marks omitted). The burden then shifts to the defendants "to show that those figures were inaccurate." *Id.* (internal quotation marks omitted). "Any risk of uncertainty in calculating disgorgement should fall on the wrongdoer whose illegal conduct created the uncertainty." *First Jersey*, 101 F.3d at 1475; *SEC v. Haligiannis*, 470 F. Supp. 2d 373, 385 (S.D.N.Y. 2007) ("The burden falls on defendants to dispel uncertainty as to the proper calculation of disgorgement and they have not done so.")

a. A reasonable approximation of Vyera's unjust gains is \$64.6 million

As Plaintiffs' economic expert Professor Scott Hemphill explains, Vyera's net profits flowing from Defendants' anticompetitive conduct are reasonably approximated at \$64.6 million. FoF ¶ 319. Professor Hemphill arrived at this calculation by creating an excess profits model with four steps:

First, Professor Hemphill determined Vyera's Daraprim revenue in the real world. Relying on Vyera's internal data, he concluded that its net Daraprim revenue from October 2018 through December 2020 was \$103.6 million. *Id.* at ¶ 321.

Second, Professor Hemphill estimated the revenues Vyera would have made in a counterfactual "but-for" world without Vyera's anticompetitive restrictions. *Id.* at ¶ 322. The most important input into this calculation is the projected date of generic entry absent Vyera's conduct. The timing of Vyera's authorized generic ("AG") entry is also a variable. *Id.*

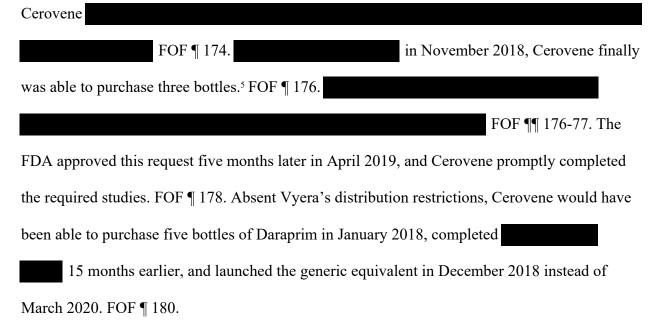
Third, Professor Hemphill determined the incremental revenue attributable to Vyera's conduct, which is \$67.6 million. This number is simply the difference between the real-world and but-for world revenue. *Id.* at ¶ 326.

Finally, Professor Hemphill calculated Vyera's excess profits by subtracting the incremental costs it would have saved by making fewer Daraprim sales. *Id.* at ¶ 327.

Incremental costs are those costs that fluctuate with the volume of Daraprim sold. They include things such as the manufacturing cost of making additional tablets and the marketing expenses that Vyera reduced after generic entry. They do not, however, include fixed costs—those costs Vyera would have paid regardless of the Daraprim quantity it sold. After deducting incremental costs, Professor Hemphill determined that Vyera's excess profits attributable to its conduct were \$64.6 million. *Id.*

In order to calculate the revenues Vyera would have made but for its anticompetitive conduct, Professor Hemphill determined potential counterfactual world generic entry dates by reviewing the record and identifying various points at which the generic applicants stated that they were delayed by obstacles attributable to Vyera's inequitable conduct. This record evidence is briefly summarized for convenience.

Cerovene Entry. The record shows that Cerovene's entry was delayed by two factors. First, Cerovene was delayed by 15 months by its inability to purchase Daraprim samples.



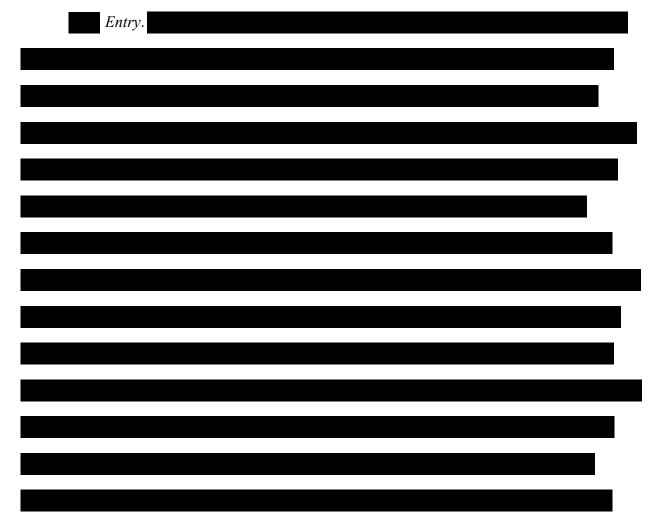
Cerovene was delayed an additional two months by its inability to obtain pyrimethamine

API from Cerovene's CEO, Manish Shah, testified that he had an agreement with

in September 2016 to supply pyrimethamine API. FOF ¶ 167. The next month,

—which was in active negotiations with Vyera for exclusivity—broke that deal and refused to supply. *Id.* Cerovene then sourced from hours, but had to complete additional regulatory submissions because manufacturing process had not yet been approved by the FDA. FOF ¶ 168. Shah will testify that had Cerovene obtained months earlier than it did in the real world. This in turn would have moved up Cerovene's development timeline by months and it could have entered the market in October 2018. FOF ¶ 181.

⁵ Cerovene was able to purchase one bottle of Daraprim in June 2018 from Because the FDA requires that bioequivalence testing be done on bottles from the same manufacturing lot, Cerovene could not combine this bottle with the three bottles it later acquired from .



Authorized Generic Entry. Vyera launched an AG version of Daraprim in March 2020, shortly after learning of Cerovene's approval. FOF ¶ 256. An AG is a generic product sold by the brand company to recapture a portion of sales that would otherwise be lost to a generic entrant. Brand companies generally launch an AG in response to generic entry. But the record shows that Vyera was not logistically ready to sell an AG until October 2019. FOF ¶ 325. Thus, if Cerovene had entered the market in October 2018, Vyera may not have been able to respond with an AG at that time and, thus, would not have made the AG sales it did in the real world. FOF ¶¶ 323, 325.

Based on the evidence concerning the timing of generic entry, it is reasonable to assume that absent Vyera's anticompetitive conduct: (1) Cerovene would have entered in October 2018;

would have entered in October 2019; and (3) Vyera would have been unable to launch an AG until October 2019. In that scenario, Professor Hemphill calculates that Vyera's net revenues from October 2018 until December 2020 would have been only \$36.1 million, and that Vyera's unjust gain is \$64.6 million.

Professor Hemphill's model is well grounded in the evidence and provides a reasonable approximation of Vyera's unjust enrichment from its anticompetitive scheme. Moreover, the model may well understate the true amount of Vyera's excess profits because it does not take into account the fact that Vyera's restrictions caused other generic companies—like Mylan—to abandon development. It is possible that one or more of these companies would have entered even earlier than October 2018 and that Vyera's unjust gain is more than \$64.6 million.

b. Defendants have failed to show this figure is inaccurate

Defendants have not criticized Professor Hemphill's model for calculating excess profits.

Instead, they offer a variety of arguments about generic entry that are based on conjecture or a misreading of the factual record. For example, Defendants' experts:

- Speculate that even if the generic developers were able to obtain samples and API sooner, the FDA might have moved more slowly in approving them so the ultimate generic entry dates might have been the same—but offer no reason to believe the FDA would have behaved differently.
- Suggest that the delays Cerovene and faced are their own fault and not attributable to Vyera's actions. In particular, they claim that Cerovene could have obtained all of the Daraprim it needed in early 2018 had it sourced through rather than As explained in Plaintiff's Joint Pretrial Memorandum at 30, however, the record shows that was more likely than and would have done so had Vyera not intervened to buy them back. FOF ¶ 175.
- Assert that, in November 2018, Cerovene could have bought five bottles instead of three from obviating the need for an FDA waiver. But Cerovene's CEO will testify that could only source three bottles. FOF ¶ 176.

Dr. Jena also quibbles with Professor Hemphill's assumptions about Vyera's pricing in the but-for world and the overall size of the pyrimethamine market. As Professor Hemphill will explain, these criticisms are inapt and, in any event, insignificant, making at most a minor difference to the total disgorgement amount. Dr. Jena makes no attempt to quantify that difference or propose an alternative figure.

Finally, Defendants have argued that, regardless of the amount of their unjust gains, Phoenixus AG and Vyera Pharmaceuticals, LLC cannot pay a judgment of \$53.1 to \$64.6 million at a single point in time and therefore should not be required to pay an award of that size at any time. But courts in this district have consistently found that a "Defendant's current financial net-worth is irrelevant to the Court's consideration of the disgorgement award." SEC v. Credit Bancorp, Ltd., No. 99-cv-11395, 2011 WL 666158, at *5 (S.D.N.Y. Feb. 14, 2011); see also SEC v. Wyly, 56 F. Supp. 3d 394, 406 (S.D.N.Y. 2014) ("For purposes of calculating" disgorgement, financial hardship does not preclude the imposition of an order of disgorgement."). It would be inequitable to withhold disgorgement "simply because a swindler claims that she has already spent all the loot." SEC v. Inorganic Recycling Corp., No 99-cv-10159, 2002 WL 1968341, *2-4 (S.D.N.Y. Aug. 23, 2002). Notwithstanding the irrelevance of a defendant's inability to pay to an award of disgorgement, Defendants have not even shown that Phoenixus AG and Vyera Pharmaceuticals, LLC are unable to pay a disgorgement award. Defendants offer only an expert opinion that these entities do not have enough liquid assets to pay a judgment between \$53.1 and \$64.6 million in the first quarter of 2022. As Plaintiffs' expert, Saul Solomon, will explain, Defendants' expert, Justin McLean, does not address how much the entities actually could pay or whether they could pay the full requested judgment over time.

3. The Imposition of Joint and Several Liability is Warranted Here

Where appropriate, courts in equity can impose joint and several liability for disgorgement awards. *See, e.g., SEC v. Pentagon Capital Mgmt. PLC*, 725 F.3d 279, 287 (2d Cir. 2013) (joint and several liability appropriate because defendants had "collaborat[ed]" on a common scheme). Joint and several liability has been upheld where, as here, the misconduct of the company and its top controlling officers are indistinguishable. *SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450 (2d Cir. 1996) ("as president, chief executive officer, and sole shareholder of First Jersey, [co-defendant] Brennan possessed control over every aspect of First Jersey's operations"). *See also 212 Inv. Corp v. Kaplan*, 847 N.Y.S.2d 905, 910 (N.Y. Sup Ct. 2007) ("[T]there is a significant body of authority holding that '[w]hen apportioning liability for disgorgement among multiple defendants, courts have the discretion to find joint and several liability when two or more individuals collaborate in the illegal conduct"); *SEC v. Haligiannis*, 470 F. Supp. 2d 373, 385 (S.D.N.Y. 2007) ("[C]ourts have the discretion to find joint and several liability when two or more individuals collaborate in the illegal conduct.")

Joint and several disgorgement orders are permissible so long as they are equitable and do not act as a penalty. Whether an award of joint and several disgorgement is appropriate in a particular case is a necessarily fact-specific inquiry. *Liu*, 140 S. Ct. at 1949 (remanding to the Ninth Circuit for a factual finding as to whether petitioners should be held jointly liable as they were married and may have shared finances.)

Under the particular facts presented here, all Defendants should be held jointly and severally liable for the total amount of disgorgement. To begin, the individual Defendants have been top officers and/or directors (FOF ¶¶ 3-4) and have been integrally involved in the wrongdoing – personally involved in critical acts. *See* FOF ¶¶ 279-285 (Shkreli), ¶¶311-317

(Mulleady)⁶. Both individuals are the two primary shareholders in the company and former CEOs. FOF ¶ 279 (Shkreli); ¶ 312 (Mulleady). Defendant Mulleady has been on the board of directors for several years – even through the filing of this action – and Defendant Shkreli is not only the mastermind and implementor of the anticompetitive scheme, but took various acts to ensure that the anticompetitive conduct would continue after his termination in December 2015 (*e.g.*, by getting Vyera to terminate his successor CEO and selecting and getting elected new Board members in 2017, by his voting and influence on the board, and by continuing to help direct the company's conduct via his influence on officers/directors like Mulleady and Mithani. FOF ¶¶ 305-310.

None of the concerns expressed in *Liu* preclude joint and several liability for a company and its top officer (or officers), as in *First Jersey*, or others who collaborated in the wrongdoing. "The amount a court may order a wrongdoer to disgorge may not exceed the total amount of gain from the illegal action, but that does not entail that the gain must personally accrue to the wrongdoer". *S.E.C. v. Contorinis* 743 F.3d 296, 305–06 (2d Cir. 2014).

Moreover, the Plaintiff States would be prejudiced if we could not enforce the disgorgement order against each of the Defendants, in full. Conceptually, there is no meaningful way to unscramble and separate the Defendants' wrongdoing, since this antitrust violation was effectuated by a large, centrally orchestrated scheme, not by individual transactions than can be somehow allocated. *See Pentagon Capital*, 725 F.3d at 287.

⁶ Mulleady ordered the audit of every pill in Fall 2017, negotiated and signed the RL Fine agreement, and bought back Daraprim from Reliant in a Starbucks parking lot. Shkreli implemented the restricted distribution scheme, orchestrated a management coup in Summer 2017 that resulting in the firing of a CEO and appointing of new Board members, and has been involved in running the company from prison, in violation of the terms of his confinement. FOF ¶¶ 279-285 (Shkreli), ¶¶311-317 (Mulleady).

C. Permanent Industry Ban

Upon finding of a violation under Executive Law § 63(12), the Court may exercise its discretion to issue a permanent and plenary ban, i.e., indefinitely excluding the individual defendants from all aspects of the pharmaceutical industry. See, e.g., People ex rel. Schneiderman v. Imported Quality Guard Dogs, Inc., 930 N.Y.S.2d 906, 907-08 (App. Div. 2d Dep't 2011) ("permanently enjoin[ing] the appellant from selling, breeding, or training dogs, or advertising or soliciting the sale, breeding, or training of dogs."); People v. Fashion Place Associates, 638 N.Y.S.2d 26 (1st Dep't 1996) ("permanently restraining and enjoining defendants ... from engaging in any and all acts directly or indirectly involving the offer of sale of real estate securities to the public."); People v. Northern Leasing Systems, Inc., 133 N.Y.S.3d 389, 412 (N.Y. Sup. Ct. 2020) ("permanently enjoin[ing] respondents from conducting the business of equipment finance leasing or collection of debts under equipment finance leases and from purchasing, financing, transferring, servicing, or enforcing equipment finance leases."); State v. Midland Equities of New York, Inc., 117 Misc. 2d 203, 208 (N.Y. Sup.Ct. 1982) ("judgment permanently enjoining [defendants] from engaging in the business of mortgage foreclosure consultation, from offering legal advice to consumers and from soliciting business for attorneys.")

Given their egregious misconduct, we seek an order imposing permanent industry bans on the individual Defendants; at a minimum, a 20-year industry ban would be appropriate in this case. To begin, there are no meaningful mitigating factors. On the contrary, there are aggravating factors. The Court has already found that Defendant Shkreli used cellphones from prison (against prison rules and court orders) to further the scheme – during the pendency of the action, no less. ECF Nos. 451, 452 (spoliation ruling). Moreover, call records and/or messages

were spoliated. *Id.* Defendant Mulleady also had his hands all over the scheme – tightening the distribution model after he rejoined Vyera in 2017 as Board member and eventually CEO (FOF ¶ 55); personally negotiating the RL fine agreement (FOF ¶¶ 121, 123), and personally traveling himself to buy back Daraprim pills at inflated prices under dubious circumstances in a parking lot. (FOF ¶ 77). This was not for the benefit of patients, of course, but rather done to keep them out of the hands of generic companies seeking them for bioequivalency testing. (FOF ¶ 122); ECF Nos. 475, 476, Ex. 17. Both individuals are poorly positioned in equity to argue for anything less than a permanent ban.

The ban should also be plenary, barring both individual defendants from the pharmaceutical industry altogether, without carve-outs. It should extend to all aspects of the pharmaceutical industry, including without limitation: brand and generic drugs and devices, at any state or research, development or sales, as well as marketing, financing, valuation or risk assessment, or any kind of consulting within the pharmaceutical industry. The order should also prohibit them from exercising share voting rights to control, influence the operation of, or vote for or against boards of directors or management of companies involved in any aspect of the pharmaceutical industry.

CONCLUSION

For the reasons set forth herein, Plaintiff States ask the Court to find that Defendants violated the state laws identified in ECF No. 86 and grant a broad injunction and order of disgorgement against the Defendants, as well as a permanent industry ban on Shkreli and Mulleady.

Respectfully submitted,

/s/ Elinor R. Hoffmann

Elinor R. Hoffmann

Chief, Antitrust Bureau

Bryan Bloom

Jeremy R. Kasha

Amy McFarlane

Saami Zain

Office of the New York Attorney General

28 Liberty Street

New York, NY 10005

Tel: (212) 416-8269

elinor.hoffmann@ag.ny.gov

Counsel for Plaintiff State of New York

/s/ Michael D. Battaglia

Michael D. Battaglia

Deputy Attorney General

Office of the Attorney General of California

455 Golden Gate Avenue, Suite 11000

San Francisco, CA 94102

Tel: (415) 510-3769

michael.battaglia@doj.ca.gov

Counsel for Plaintiff State of California

/s/ Richard S. Schultz

Richard S. Schultz

Assistant Attorney General

Antitrust Bureau

Office of the Attorney General of Illinois

100 W. Randolph Street, 11th Floor

Chicago, IL 60601

Tel: (872) 272-0996

Richard.Schultz@ilag.gov

Counsel for Plaintiff State of Illinois

/s/ Jessica V. Sutton

Jessica V. Sutton

Special Deputy Attorney General

North Carolina Department of Justice

Consumer Protection Division

114 West Edenton Street

Raleigh, NC 27603

Tel: (919) 716-0998

jsutton2@ncdoj.gov

Counsel for Plaintiff State of North Carolina

/s/ Beth A. Finnerty

Beth A. Finnerty

Assistant Chief, Antitrust Section

Office of the Attorney General of Ohio

30 E. Broad Street, 26th Floor

Columbus, OH 43215

Tel: (614) 466-4328

Beth.Finnerty@OhioAGO.gov

Counsel for Plaintiff State of Ohio

/s/ Joseph S. Betsko

Joseph S. Betsko

Senior Deputy Attorney General

Pennsylvania Office of Attorney General

Antitrust Section

Strawberry Square, 14th Floor

Harrisburg, PA 17120

jbetsko@attorneygeneral.gov

Counsel for Plaintiff Commonwealth of Pennsylvania

/s/ Tyler T. Henry

Tyler T. Henry

Assistant Attorney General

Office of the Attorney General of Virginia

202 North 9th Street

Richmond, VA 23219

thenry@oag.state.va.us

Counsel for Plaintiff Commonwealth of Virginia

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